FOOD AND DRUG ADMINISTRATION

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CENTER FOR DRUG EVALUATION AND RESEARCH

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PUBLIC HEARING ON

OTC PART 15

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WEDNESDAY
JUNE 28, 2000

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The Public Hearing was held at 8:30 a.m. in the Ballroom of the Holiday Inn, Two Montgomery Avenue, Gaithersburg, Maryland, Dr. Robert DeLap, Director, Office of Drug Evaluation V, CDER, presiding.

FDA PANEL:

JANET WOODCOCK, M.D., Director, CDER
RUSSELL CAMPBELL, Office of the Commissioner, Consumer Affairs
DAVID FOX, J.D., Office of the Chief Counsel
DIANNE MURPHY, M.D., Acting Director, Office of Review Management
ROBERT TEMPLE, M.D., Assoc. Director for Medical Policy, Director, ODE I
JOHN JENKINS, M.D., Director, ODE II
FLORENCE HOUN, M.D., Director, ODE III
ROBERT DeLAP, M.D., Director, ODE V
CHARLES GANLEY, M.D., PhD, Director, Division of OTC Drug Products
GARY CHIKAMI, M.D., Director, Division of Anti-Infective Drug Products
LOUIS CANTILENA, M.D., PhD, Acting Chair, Nonprescription Drugs Advisory Committee
SANDRA TITUS, PhD, Executive Secretary Nonprescription Drugs Advisory Committee

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I-N-D-E-X

I-N-D-E-X (continued)

P-R-O-C-E-E-D-I-N-G-S

(8:38 a.m.)

MODERATOR DeLAP: Well, we have a busy agenda. Good morning, and welcome to our open public hearing regarding the regulation of OTC drug products.

I'm Dr. Bob DeLap. I work at the FDA, and I am going to be moderating the session.

The purpose of our hearing is really to gather more information and views from people who are affected by our regulation of OTC drug products, which is just about everybody. We recognizes that health care in the United States is changing, and more drug products are being marketed directly to consumers, and we expect that trend will continue.

Again, we want to make sure that we have as much information and advice as possible so that we can make the best decisions from our end as time goes by. Next, please.

The law and regulations provide for a few reasons for which a product may not be available over-the-counter. Those are products that have potential for addiction or are habit forming; products that inherently have safety issues or conditions of uses of product present issues that require supervision by a licensed practitioner for safety; and finally products

that are restricted to prescription status under a FDA approved marketing application.

There are two primary mechanisms available for bringing products OTC in this country at this time. There is the OTC Monograph System, also known as the OTC drug review, which goes back many years and provides a mechanism for marketing of products following monographs published by the FDA that allows people to market products without pre-clearance, as long as they follow the directions provided in the monographs. Next.

Then the other primary mechanism for OTC drug marketing is the New Drug Application. This entails generally switching a product from prescription-only status to an over-the-counter status. Considerations here include safety and effectiveness in the OTC use and whether clear and understandable labeling can be developed for self-medication without help of a health professional.

As we said in the Federal Register notice announcing this meeting, in light of the continuously changing health care environment, including the growing self-care movement, the agency continues to examine its overall philosophy and approach to regulating OTC drug products.

We are interested in soliciting information from and the views of interested persons, including health professional groups, scientists, industry, and consumers on the agency's regulation of OTC drug products.

Scope of the hearing, as outlined in the notice: Criteria for OTC availability of drug products; classes of products appropriate for OTC; consumer understanding; selection of treatment; OTC marketing systems; and FDA's role in switches.

Regarding the first element, the questions that we raised in the FR notice were: What criteria should FDA consider in deciding on the OTC availability of drug products? What kinds of products are or are not appropriate for OTC distribution? What types of illnesses are or are not suitable for OTC drug products? How should individual risks/benefits and public risks/benefits be balanced in decisions on OTC marketing?

Regarding classes of products appropriate for OTC, we asked: Are there specific classes of products that are not currently marketed OTC that should be? Which ones, and why? We also asked, are there specific classes of products that should not be available OTC, and what specific concerns do those

classes raise?

We included with that last point a list of conditions that we had heard discussion of bringing OTC for purposes of discussion.

The third area of interest to us was consumer understanding: How can FDA be assured that consumers will adequately understand drug benefits and risks and will be able to use products safely and effectively in the OTC setting? What methodologies can be employed to evaluate consumer understanding? How can we convey efficacy information, for example, for products that are marginally effective or products that are used for preventive indication, and can we label prevention type products in a way that would not encourage ill advised behavior, such as not good behavior for one's personal health followed by using a medicine to try and make up for it?

Selection of treatment: How can we ensure good selection when there are both OTC and prescription treatments available for the same illness? When consumers are confronted by having a medicine available over-the-counter and knowing that there are medicines available by prescription only, how can we ensure that the consumers have the information they need so that they can decide on the

best course of treatment for themselves? Are there public health concerns here?

Within a therapeutic class, should the first drug to enter the OTC marketplace be the best drug? How should the availability of a better OTC product affect the status of products already available OTC for the same indication?

Then with respect to OTC marketing systems: Is the current structure for marketing OTC products in the U.S. adequate? What lessons can we learn from different OTC marketing systems?

FDA's role in switches -- this is the last of the six categories of questions we had: Under what circumstances should FDA actively propose OTC marketing for a drug in the absence of support from the drug's sponsor? Should FDA be more active in initiating switches of prescription products to OTC use?

Now the schedule that we have, which was available outside as people were coming in, divides the presentations into several sessions, and this schedule was dictated by the requests that we received. So there are certain categories for which we received a lot of requests to speak and other categories where we didn't receive requests, and

that's reflected on the schedule here. Next.

The format for the open public hearing is that the hearings are transcribed. Speakers are entitled to use their time as they wish. We only request that the hearing be orderly.

If a person is not present at the scheduled time of their presentation, we will try to accommodate them at the end of the hearing, but we will try and stay on schedule.

Persons serving on the panel may ask questions of speakers. In these kinds of public hearings, persons in the audience are not allowed to interrupt or question speakers.

Finally, persons in the audience who do wish to speak and are not on the schedule may request time to speak at the end of the scheduled presentations.

Now at this point I'm going to ask the members of the panel to briefly introduce themselves and just a one-sentence description of their position in the agency. Perhaps I'll start. Sandy, can I start with you?

DR. TITUS: I'm Sandy Titus, and I'm the Executive Secretary for the Nonprescription Drugs Advisory Committee.

DR. GANLEY: I'm Charlie Ganley. I'm the Director of the Division of Over-the-Counter Drugs.

DR. CANTILENA: Hi. I'm Lou Cantilena, head of Clinical Pharmacology at the Uniform Services University and a member of the OTC Advisory Committee.

DR. FOX: Hi. I'm Dave Fox. I'm an Associate Chief Counsel in FDA's Office of the Chief counsel.

DR. CHIKAMI: I'm Gary Chikami. I'm the Director of the Division of Anti-Infective Drug Products.

DR. MURPHY: I'm Dianne Murphy, and I'm the Acting Deputy Director of the Office of Review Management.

DR. WOODCOCK: I'm Janet Woodcock. I'm Director of the Center for Drug Evaluation and Research.

DR. TEMPLE: I'm Bob Temple. I'm Associate Director for Medical Policy and Director of the Office of Drug Evaluation I.

DR. HOUN: I'm Florence Houn. I'm Office Director for Drug Evaluation III.

DR. JENKINS: I'm John Jenkins. I'm the Director of the Office of Drug Evaluation II.

DR. KWEDER: I'm Sandra Kweder. I am the

Acting Director of Office of Drug Evaluation IV.

DR. CAMPBELL: I'm Russell Campbell, Senior Consumer Affairs Specialist, representing Patricia Kuntze, the Associate Commissioner for Consumer Affairs.

MODERATOR DeLAP: We also have a few guests that are here to hear what is presented at this session, members of our Nonprescription Drug Advisory Committee, and if I could ask them just to briefly stand and identify themselves.

(Guests introduced.)

MODERATOR DeLAP: I believe that was my last overhead. Yes. Okay, well then, the only other thing I will remark to all the speakers is that we do have one of those troublesome little signal lights here as to how many minutes are left in the presentation time. We will try and do our best to stay on schedule, and we ask you to observe the lights and try and stay within the allotted time.

With that, I will turn the podium over to our guest speakers here. The first session is on process issues, and I believe Dr. Michael Maves from the Consumer Healthcare Products Association will be speaking first.

DR. MAVES: Thanks, Bob. Good morning.

My name is Dr. Michael Maves, and I am the President of the Consumer Healthcare Products Association and a practicing physician at the Georgetown University Medical Center.

Our presentation today will be in three parts. I will be addressing the overall policy issues of importance to the industry, while Ms. Bachrach will speak to selected legal issues, and Dr. Soller will address the scientific and regulatory perspective.

CHPA is the 199-year-old trade association representing the manufacturers and distributors of nonprescription medicines and dietary supplements. CHPA members represent over 90 percent of retail sales in the OTC marketplace. We have worked collaboratively with the FDA, with consumers and the administration over the years on all aspects of OTC drug development, labeling, manufacturing and packaging.

Let me begin my presentation where I will end. Self-care with OTC medicines is here to stay.

Secondly, the switch of drugs form prescription to nonprescription has been phenomenally successful.

Finally, over the past 25 years, consumers, FDA and the industry have faced

increasingly difficult challenges regarding OTC availability of prescription products. Together, we have created novel solutions to difficult problems, and the consumers in the United States have benefitted form these developments.

We speak about an OTC perspective within the industry. This perspective, which we feel should be shared by all concerned parties, recognizes the forces behind the self-care movement and captures the impetus for the development of new OTC products.

As I'm sure you're aware, consumers are extremely interested in their own health care. For instance, 60 percent of adults follow news stories about health, more than business, more than sports.

Secondly, consumers benefit from self-care. Access to self-medication options empowers consumers and effectuates their desire to take control of their own conditions. OTC medicines provide convenience, cost and time savings.

Consumers turn to OTC self-care for 38 percent of all their health care problems they experience. Yet for this vast volume, OTCs take up less than two cents of every health care dollar.

The resource savings to the health care system through responsible self-medication allows

better allocation of limited health care resources and physicians' time to important issues beyond the scope of self-care.

Self-care with OTC products spans a broad range of conditions and diseases, ranging from acute conditions to recurrent conditions which will require an initial physician diagnosis. Chronic disease prevention strategies may also involve the use of things such as sunscreens to prevent cutaneous solar damage and the development of skin cancer.

Finally, adjunctive treatment with OTC medicines, coupled with lifestyle changes, can make a real difference to patients who, for instance, are attempting to stop smoking.

Next, industry experience has shown that consumers use the OTC label and responsibly self-medicate. Ninety-five percent of consumers read the label prior to the first product use, and there is a high level of label comprehension.

Importantly, OTC does not necessarily mean that the MD is out of the picture. In fact, for conditions such as vaginal yeast infections, an important part of the OTC treatment program is the initial diagnosis of the condition by a physician.

Finally, the OTC industry and CHPA are

proud of their leadership in providing comprehensive, easily understood information on the package label.

The potential for further self-care empowerment of consumers is based upon a scientific paradigm which defines specific target populations with readily recognizable conditions, previously diagnosed conditions, or self-diagnosable diseases, and determining which drugs at the appropriate dosage and with the appropriate labeling can provide a reasonable expectation of benefit with a low potential for toxicity.

These new products are best determined on a case-by-case, data driven approach that is initiated by the drug manufacturer, in collaboration with the FDA, in such a way that the individual, not comparative, merits of the switch are assessed through the appropriate research methodologies.

This type of perspective has provided the consumer with a wide variety of products and some truly remarkable success stories for all of us. Over 80 ingredients, dosage forms and strengths have been switched from Rx status or introduced as new OTC drugs since the start of the OTC Review in 1972, accounting for over 700 marketed products. Some examples are listed here.

To summarize this point, the OTC perspective or approach recognizes all of these features: Consumers are interested in health care and benefit from self-care; self care is potentially applicable to a wide variety of conditions; consumers read and use the OTC label and can responsible self-medicate; a scientific, research driven paradigm drives the evaluation of new OTC products which should be evaluated on a case-by-case basis using company provided data from carefully designed research questions.

The process allows changes in labeling as further information develops. Success will ensue from such a perspective being jointly pursued by the FDA and industry in a collaborative fashion to benefit the consumers who use these products.

I'd like now to address three FDA questions. FDA asked whether preventive claims can promote ill advised behavior. Let's step back.

How patients and consumers behave rests with them, irrespective of our best intentions. This is not unique or limited to OTC products. We feel that the more relevant questions are if this does happen, to what extent does it occur, and how would OTC availability provide a similar or greater public

health benefit to consumers than prescription alternatives. Again, we would feel that this should be evaluated on a case-by-case specific basis.

FDA asks about the impact of co-existing treatments, including how to determine appropriate self-selection of OTC and Rx treatments.

This is not a new issue for both self-care and physician directed care. We already have the availability of both Rx and OTC products with the same ingredients but with different formulations, strengths or indications.

In fact, a casual perusal of the PDR reveals many conditions which have both Rx and OTC options available to the patient and to the consumer. Many conditions exist across a spectrum of severity and symptomatology where it is entirely appropriate to provide products for both self-care and physician directed care.

FDA asks about how the availability of a better OTC product would affect the status of products already on the OTC market for treatment of the same condition.

It's well known that individuals, consumers, patients and physicians, vary in their response and preferences for different treatments.

This can lead to individual differences in compliance that may further vary the response to treatment.

Therefore, we feel that the definition of "better" is not easily defined for this purpose. For that matter, on the prescription side, medical practice welcomes a wide armamentarium where many older drugs play a critical role. We feel that consumers should have the same choice.

In concluding my portion of the comments of our remarks, let me again emphasize that self-care is here to stay. Consumers demand it. They are aware of it, and want more control over self-care.

Secondly, the switch of drugs from prescription to nonprescription has been phenomenally successful. This success has stemmed from the collaborative efforts of the industry and FDA working together to evaluate the specific merits of a case and make a scientifically documented decision, to the benefit of the consumers we serve.

Finally, if past is prologue to the future, over the past 25 years, FDA and industry have faced increasingly difficult challenges regarding the availability of prescription products. Together, we have created novel solutions to difficult problems. Consumers have benefitted from this collaboration in

the past and will continue to do so in the future. Thank you.

MS. BACHRACH: Good morning. I'm Eve Bachrach, General Counsel of the CHPA. I will focus on four issues this morning. First, who should initiate a switch? Second, the role of comparative assessments. Third, the use of a single brand name to identify a line of OTC products; and fourth, the two-class system for distributing drugs in the United States.

FDA asks if it should propose OTC marketing in the absence of support from the drug sponsor and, more generally, if it should be more active in initiating switches.

Today virtually every switch is accomplished through the new drug approval process. This makes public health sense. The company that developed the drug in the first place and obtained the NDA for the Rx drug knows the most about the drug.

The company is also in the best position to design and perform the studies necessary to establish whether a drug can be adequately labeled for OTC use.

Where FDA believes that a drug should be considered for OTC use, the agency should consult with

the company about this. However, the suggestion that FDA might switch a drug without the company's active participation or, worse, over its opposition could lead to the switch of drugs that should remain prescription.

The only instance where FDA undertook to switch a drug without the active support and participation of the company was metaproterenol. The agency soon reversed its decision, acknowledging that it had not taken into account all of the pertinent information and views.

Valuable lessons were learned from that experience, and the switch process has since evolved to a collaborative approach between the NDA company and FDA. This has been successful and has benefitted consumers.

If a switch were to be undertaken without consent of the NDA company, the Act requires that due process be followed. The Rx legend is part of the approved NDA. To remove it over the objection of the company, FDA would have to follow notice and hearing requirements.

Neither the switch regulation procedure nor OTC Review rulemaking could be substituted for statutory hearing rights. In any event, the switch

regulation procedure is an anachronism in today's environment, because it only provides for removal of the Rx legend, not for development of extensive data and labeling needed to support OTC use.

In addition to due process, almost any switch would also have to rely, at least in part, on data submitted as part of the original NDA for the prescription drug. The company has proprietary rights in its NDA data which could not be used without its consent, regardless of the regulatory switch option used.

For all of these reasons, FDA should continue to rely upon the NDA company to initiate the switch process.

FDA asks about comparative assessments. Should the "best" prescription drug in a class be switched first? Should older OTC therapies be taken off the market after "better" ones are introduced?

Consumers benefit from the widest possible availability of drug products that are safe, effective, and properly labeled. Because of individual variability and preference, what is best for one person may not be for another.

The process of comparing drugs to one another is a decision for the consumer. FDA should

not foreclose potentially useful options. Rather, FDA should evaluate drugs on their individual merits.

The statute was carefully and deliberately written to provide that drugs should be made available to consumers if FDA concludes that they are safe, effective, and labeled properly. If a drug meets these criteria for OTC use, FDA must and should approve the application, regardless of whether the agency believes that other products are "better" in one respect or another.

Once approved, a product can only be withdrawn based on a similar finding that it is no longer safe and effective. The availability of "better" drugs is not a criterion for withdrawal.

When genuine safety or effectiveness issues are presented with a marketed product, industry has a long history of working cooperatively with FDA in the public interest through labeling changes and, where appropriate, by taking products off the market.

It is good public health policy for consumers to have access both to new switch drugs and to older drugs that may be appropriate choices. For that reason, there is nothing in the statute that permits FDA to make the sort of comparative assessments contemplated by the questions in the

hearing notice.

FDA asks, third, how to assure that consumers understand the benefits and risks of particular products when the same brand name is used for a line of OTCs.

Use of a family brand name for a line of drug products benefits consumers who use the brand to identify trusted product sources. Manufacturers are able to develop useful new products based on an established brand heritage, thus expanding the range of consumer self-care.

FDA also recently addressed the issue of product selection through its OTC label format rule, which requires active ingredients to be identified first in the "Drug Facts" section of the labeling. The agency said that this placement will help ensure proper product selection, especially for product line extensions.

Brand name line extensions are beneficial to the health care system by contributing to the OTC armamentarium. We also believe that any attempt by FDA to restrict brand name line extensions generally would violate First Amendment protection for truthful and nonmisleading commercial speech, and would violate the property rights of manufacturers in their trade

names. FDA precedent also makes trade name restrictions a matter of last resort.

Finally, FDA asks if we can learn from countries where nonprescription drugs are sold "behind the counter."

Convenience and access are hallmarks of the effective self-medication system in the United States. A third class of drugs would reduce both without providing a benefit to consumers.

A third class of drugs in the U.S. has been exhaustively studied for 120 years and rejected. The definitive study was undertaken by the U.S. General Accounting Office. In its 1995 report, the title tells the story: "Nonprescription Drugs: Value of a Pharmacist-Controlled Class Has Yet to Be Demonstrated."

Since 1974, FDA has repeatedly rejected a third class of drugs on the grounds that a public health benefit has not been demonstrated. Both the agency and the Department of Justice have acknowledged that FDA lacks statutory authority to establish any such class.

In short, the U.S. system of unrestricted OTC drug distribution works, and other countries are starting to follow America's lead.

In conclusion, the public interest and public health support switches initiated by the company with the NDA, the part with the most comprehensive knowledge about the drug.

The public health is best served by having the broadest range of safe and effective OTC therapies available.

Use of a brand name to identify a line of products facilitates product choice and enables manufacturers to develop and bring to market useful new self-care products.

Finally, a third class of drugs has been exhaustively studied and rejected for over a century on the ground that no public health benefit has been demonstrated. It would be a backward step for the U.S. to consider restrictions on OTC availability as the rest of the world is starting to follow America's lead by expanding unrestricted access to OTC drugs.

DR. SOLLER: Good morning. My name is Dr. Bill Soller. I'm Senior Vice President and Director of Science & Technology for the Consumer Healthcare Products Association.

I've been involved in the OTC industry for over 20 years, and over that time have consulted with many of our members on many switches that have been

undertaken during that time.

I plan to concentrate on three areas of FDA's questions by describing the Rx to OTC switch process, specifically covering switch criteria, consumer understanding, and category exemptions.

FDA asks what criteria the agency should use for switch. We interpret switch criteria to mean the standards for making the benefit/risk decision for OTC availability.

Switch criteria should be the current statutory and regulatory criteria that have been the basis for the many successful switches undertaken since the start of the OTC Review.

The foundational statutory criterion is basically the demonstration that labeling can be written for consumers to use a product safely and effectively without a prescription.

On this statutory basis, the regulatory definitions of safety, effectiveness and labeling were developed in 1972 as the scientific underpinning for the OTC Review. In practice, they have been used subsequently as the basis for evaluation of OTC New Drug Applications.

Specifically, the regulatory interpretation of the statute interprets safety,

effectiveness and labeling in relative terms, meaning a reasonable expectation of effectiveness, a low incidence of side effects, a low potential for abuse, not an absence of toxicity or an expectation that 100 percent of the target population will have a 100 percent benefit 100 percent of the time.

These regulatory criteria are fulfilled through the application of the basic principles of toxicology, clinical pharmacology and epidemiology, using the standard scientific/regulatory paradigm, which is the case-by-case, weight of the evidence, data driven, dialogue driven approach that we use as scientists to determine drug availability.

Specifically, companies are well equipped to address the sorts of potential issues that typically arise in the context of OTC availability and switch. Companies consider potential safety issues with respect to potential toxicities which are often already worked out in the parent drug's New Drug Application, and safety issues relating to potential therapeutic hazards, including issues associated with misdiagnosis, potential treatment failure, incorrect use, and drug interactions.

Key effectiveness issues are also considered, and companies consider the ability of the

label to convey core communication objectives of safe and effective use of the product by consumers without a prescription. After all, this is the basic statutory criterion.

Based on this framework, the compulsory benefit/risk assessment integrates safety, effectiveness and labeling within the question: Is the benefit of self-care through OTC availability worth the risk of access without a prescription?

Because the switch process is case specific, it often requires substantial data development. This is best developed through a company initiated approach that includes early and frequent dialogue with the agency during the OTC R&D process.

Case specificity is universal to switch, often necessitating a data intensive approach and close company-agency interaction. For example, quit rates for Nicotine Replacement Therapy were much better in high support settings versus lower support settings. Yet the limitation to access to prescriptions was actually thwarting usage of NRT and, therefore, total quit rates on a population basis. Actual use studies showed OTC access could resolve this problem.

Pediatric ibuprofen involved the largest

trial in the company's history, and this was one of our largest members, to assess the relative risk of rare side effects when used a sa fever reducer.

Vaginal antifungals posed the question of the ability of women to recognize symptoms of recurrent vaginal candidiasis after a physician diagnosis, and the core issue for OTC Cimetidine related to potential drug-drug interactions.

We can expect, therefore, that every future switch will have its own unique set of issues that can only be resolved by a data driven, dialogue driven approach.

On the subject of consumer understanding FDA asks: How can it be assured of consumer understanding of the benefits and risks of specific OTC drug products and the ability of consumers to use OTC products safely and effectively?

FDA can continue to gain assurance by using the established switch process and the consumer behavioral research studies that have been refined over the last decade to address case specific switch questions.

Consumer behavioral research includes attitudinal and comprehension as well as observational research. Examples include actual use studies, label

comprehension studies, research defining OTC target populations, research on educational programs and materials that form part of the labeling of the switch candidate.

Any and all of these studies can be essential to the OTC benefit/risk decision. FDA's questions suggest a need for further dialogue on this matter, and we ask for that at this meeting.

FDA also asks: What types of drugs or classes of products should not be available OTC?

In the context of the statutory criteria for OTC-ness and the established switch process, FDA should not create presumptive negative lists.

As a conceptual matter, no drug or category of drugs should be listed as off limits to scientific research when we cannot predict technological developments or the results of future studies. To do so would be in conflict with the statutory criterion for switch and the associated case by case, data driven scientific/regulatory paradigm.

Remember, eleven years ago at a national symposium, it was predicted that H2 blockers would not go OTC. Yet today, through a collaborative effort by companies and FDA, they are a major part of the OTC antacid/acid reducer category. The point is,

presumptive negative lists should be avoided.

In summary to our remarks: The switch process has been very successful in providing significant therapeutic benefits to consumers.

FDA must use the statutory criterion for switch and should continue to use the regulatory definitions of safety, effectiveness, and labeling, practice the scientific/regulatory paradigm, review drugs on an individual basis, and avoid presumptive negative lists.

We seek additional dialogue on consumer behavioral research. Switch should be initiated by the NDA company who has the most knowledge about the drug.

A third class of drugs has been thoroughly reviewed and rejected for over a century on the grounds that no public health benefit has been shown. Most importantly, we should seek collaborative, not confrontational, approaches for the company-agency dialogue that is vital to creating a thorough, yet reasonable, OTC R&D program to address future switch proposals. Thank you very much.

MODERATOR DeLAP: Thank you, Dr. Soller. At this point I'd like to hear any questions that members of the panel may have for CHPA.

DR. TEMPLE: This is a question for Ms. Bachrach. You emphasized that the switch initiative should pretty much always come from the company. There is legislation, a statute that says that -- the Durham-Humphrey Act that says the drugs that can be appropriately used by patients should be. At least, that's how we read it.

Sometimes companies defer the desire to switch, because they are not ready, because of commercial considerations. Don't you think there is some role under that law or some obligation by the company under that law that should make us be more bold? You need to go to a mike or it won't be recorded.

MS. BACHRACH: Well, Dr. Temple, I would first preface by saying that the Durham-Humphrey amendment was designed to address a system where there was a number of drugs on the marketplace where the Congress and the agency were trying to bring some kind of consistency to their regulation. There would be drugs that were both, identical drugs sold by two companies. One was prescription; one was sold OTC.

It had a very narrow purpose at the time. The switch -- That switch regulation procedure that you referred to as a result of Durham-Humphrey really

is long since become an antique museum piece in the current environment.

It was last used in 1971, and the only ability it provides is to remove the Rx legend. It doesn't provide for what we now have long since come to recognize as necessary to develop the kinds of data that Dr. Soller was describing to assure appropriate safety, effectiveness and labeling for an OTC drug, which usually is at a different -- in today's environment, usually sold at a different dose and for different indications.

In terms of the company, the company clearly has the most knowledge, the most knowledge both in terms of its development of the Rx drug NDA in the first place, and then during the course of the marketing of the Rx drug it is very typical for the company to have conducted dozens, if not sometimes hundreds, of studies that may bear on aspects of the drug's use that will have accumulated an important decision making factor in whether or not and when that particular drug is appropriate to switch OTC.

So the agency certainly has a role in approaching a company and asking where they believe a particular drug may be appropriate for OTC, but to undertake on its own initiative without active

participation and support of the sponsor, I think, would not be wise in today's environment.

DR. TEMPLE: Okay. That's fine. Not to focus on particular drugs, which will be discussed later, there are some circumstances in which you might not even think that use studies are necessary and things like that. So I guess you would say that there is more of a role for the FDA in that.

MS. BACHRACH: I would say it would be appropriate to consult with the company on that.

MODERATOR DeLAP: I had one other point that I would like to hear a little more elaboration on.

There was discussion of how we should take into consideration the availability of -- the continued availability of older products, for example, when a newer, better product comes along. One of the points that I thought I heard was that, even if the older product presented some kinds of safety problems, that there would likely continue to be a role for it, at least for selected individuals.

I know that, clearly, in the prescription drug process, we have at times had products go off the market because of safety issues, and part of that decision making process was that there were now newer,

better alternatives.

I'd like to hear a little bit more again as to what the rationale would be for keeping an older product in the marketplace that has more safety problems.

DR. MURPHY: Bob, could I ask them to add to that, because I think it's the same category. They have addressed many of the benefits and mentioned not a lot on risk. They might want to incorporate that into their comments, what they see as some of the risks.

MS. BACHRACH: Well, Dr. DeLap, with respect to older drugs, whether they are OTC or prescription, if there is a legitimate safety question that arises, regardless of comparative benefits of drug A versus drug B, if drug A has substantial safety questions about it, the agency certainly should raise those and, if they can be addressed, as sometimes they certainly can be through labeling, that would be the appropriate way to approach the product.

It is certainly a matter of last resort where benefit/risk ratio is such that the risks outweigh the benefit that pulling a drug from the market, particularly an older OTC, would have to be considered.

Certainly, in the case of OTC drugs, we are dealing -- The neutral principle is that these drugs have a very wide margin of safety. So it would be a rare circumstance under which such a drug would present such a significant safety problem that removal from the market should be a consideration, quite apart from the issue of a comparative -- comparative questions of whether that drug is better than another one.

In the context of how the questions were framed in your hearing notice, you spoke generally about should drugs be removed if, quote, "better" drugs come on the market. In the context of your particular question, that is not contemplated under the statute, in our view, and we will certainly be addressing that in greater detail in our written comments following the hearing.

DR. SOLLER: Bob, I have a brief add-on. If the agency has a legitimate safety concern, and this has happened throughout the OTC Review and subsequently to the end of the panel discussions in the Eighties, then typically the agency has come forward and asked for information on it.

What has happened through the OTC review is the development of a very well worked out policy to

manage that, and it has been used over and over again, and it's the policy about availability, the policy about warnings. That is that warnings, availability must be scientifically documented, clinically significant, and important to the safe and effective use of the product by the consumer.

This three-part hurdle has been played out time and again through the advisory committee meetings dealing with currently marketed drugs as well as switch drugs. So you have a policy and process in place that's been working quite well and, I would envision, would continue to work quite well in the future.

MODERATOR DeLAP: Okay. Well, thank you very much. One more question?

DR. TEMPLE: One of the major points made was the importance of the consumers' ability to choose and their responsibility for choosing among available therapies.

If you got to a relatively complicated situation, like cholesterol lowering agents -- not to raise that issue prematurely -- what exactly do you contemplate as the contents of labeling? Would it say this one hasn't been shown to have any effect on survival, but others have?

I mean, what's a realistic level of information to provide in labeling? I guess I should note that in the past there's been some reluctance to put efficacy data in labeling for OTC drugs on the grounds that it wouldn't be well interpreted, could be misleading, and so on.

DR. MAVES: Thanks. I appreciate that. Without getting into specifics, I think the point that we were trying to make is this, that if you look at each one of the new switches that have come up over the past 25 years, in almost every instance the need for new labeling or a way to explain to the consumer in an easily understood fashion has been part and parcel of that particular switch process.

If you look back at things like nicotine replacement therapy where there's a rather exhaustive type of instruction for the particular consumer that's necessary so they can intelligently use the product, we've seen time and again that that kind of inventiveness can be put together, that we can have those kind of instructions available to the consumer, and that they, in point of fact, can use these products in an intelligent, reproducible fashion.

So without getting into specifics with this and saying, well, gee, exactly what would the

label look like, I think I have a lot of faith both in the industry and in the consumers that together we can come up and find appropriate labeling that can be used, that can intelligently communicate the necessary information to consumers to use those products on an OTC basis.

MODERATOR DeLAP: Okay. We'll move on to the second presentation. Oh, sorry.

DR. FOX: Just a quick question. Will your written comments include a thorough analysis of the argument that a sponsor has certain due process and proprietary rights in maintaining its product Rx, if it so chooses?

MS. BACHRACH: Yes.

DR. FOX: Looking forward to it.

MODERATOR DeLAP: Okay. I believe we are now ready then for Mr. Donegan and The Cosmetic, Toiletry and Fragrance Association. Tom?

MR. DONEGAN: Let me stake out my ground with a couple of products here, and I'll come back to those. Those will be relevant very quickly.

I'm Tom Donegan. I'm General Counsel of The Cosmetic, Toiletry, and Fragrance Association, and I will be joined shortly by Dr. Jim Leyden of the University of Pennsylvania School of Medicine who is

going to talk about some of the sunscreen issues that we have here.

Before I start, I would like to congratulate FDA on holding this hearing. One of my points is going to be openness in the OTC process, and I think just this kind of dialogue and as many other dialogues as we can have about the process and ways to change things and make them work better is very important. May I have the next slide, please.

Michael Weintraub used to always like to ask at the beginning of meetings on OTC drugs, well, what are the cosmetic people doing here? Well, the first thing I want to do is explain that to you.

We are a trade association that was founded in 1894. We represent about 600 companies, 300 of whom manufacture products, and many of these members manufacture not only cosmetics but drugs as well. In fact, many of these products are regulated as both cosmetics and drugs, and have to comply with both regulatory structures.

We are here to discuss not the switch issue but the monograph process, the OTC Drug Review, which started in 1972, which we feel is very important, particularly to our products. There are still many products subject to ongoing monographs some

28 years later, and this provides a way for people to market products in compliance with the monograph, regardless of whether they have the resources to go through the NDA process and to sponsor an NDA. Next slide, please.

One thing that strikes me as we look at this hearing and the subject matter that you are covering is that the field of OTC drugs is getting broader and broader from both ends. You're looking appropriately at Rx to OTC switches which allow flexibility, that allow consumers to have products that are available, and to have choice where the facts are appropriate.

Well, also at the other end of the spectrum many drug products are now being marketed in cosmetic vehicles, and so they are sold in cosmetic settings in products that provide cosmetic benefits as well as drug benefits. Our point is that greater flexibility should be allowed for those products and the way that they are labeled through the monograph process. Next slide.

What are cosmetic drugs? This gives you a list of the types of products I'm talking about. It's not all-inclusive, but we're talking about sunscreens in cosmetic products, a foundation product

that provides SPF protection.

We're talking about antiperspirants which are drugs, because they are an antiperspirant, and they are cosmetics because they are a deodorant -- these, by the way, are convenience sized packages, which I'll come back to later on in another point -- anti-dandruff shampoos, oral care products, and a variety of other products. Next slide, please.

Why are they different? They are sold through different marketing channels. For example, many cosmetic drugs are sold through department stores, not a normal vehicle for many OTC drugs. In many cases, they are purchased primarily for their cosmetic benefit, but they do provide important drug benefits as a secondary benefit.

The broad consumer availability of these products provides, we believe -- and Dr. Leyden will talk about this more -- an important public health benefit, particularly for products like sunscreens, and they come in small packages, convenience sizes which are essential for the consumer to be able to use them in many different settings, at work, while they are traveling, a variety of other settings. Next slide, please.

Many of these products, not all but most

of them, come to market through the OTC Drug Review, which as you all know, started back in 1972, and we are now in 2000, and we expect it to go for a while.

You're going to hear from many people during this hearing who were there at the beginning of the OTC Review. I hope that there will be some of us who will survive to see the end of the OTC Review, but quite seriously, I raise the question, should it end or should that just be an ongoing process where we are constantly revising and tweaking and looking at new products, etcetera? It's provided an important function. Next slide, please.

The problem with the monograph process -- and I don't think it started out this way or it certainly didn't start out with these intentions -- is that it's far too slow. It's taken much too much time to come to final conclusions on some of these products.

Typically, when you look at monographs like sunscreens or skin protectants or others, it's been a stop and start process. It's a lot of activity, and then years of seeming inactivity before it starts up again.

I think there's a failure within FDA to distinguish between NDAs and the monograph process.

In fact, I've been somewhat disturbed to hear recently talked that the monograph process should be more like the NDA process. I think quite the opposite. I think this needs to be an open process where the agency holds itself open to learn as much as possible about the product category and how it has evolved.

Evolution of the products is important here, particularly given the tim frame that's been involved. Some of these product categories -- and again Dr. Leyden will talk about sunscreens -- don't look anything at all like they did back in 1972 or '75 or whenever the process started.

There's a need during the ongoing monograph process to recognize new ingredients, to recognize new product forms, and to take all of that into account. Next slide, please.

I think the agency has found it difficult to update its expertise on these over-the-counter drug products. I don't know whether that's because of resources or lack of focus or what the issue may be, but the agency should be on the cutting edge, certainly, of the science, and they ought to also be up on formation technology, on testing methods, on the whole variety of issues that have to be resolved in the context of a monograph.

Our feeling is many times that's not the case, that the agency is looking at a product category in 2000 through 1977 glasses, and you're seeing a distorted picture. You're not really seeing what's out there. You're not seeing what the consumer is using. You're not seeing the products that the consumer needs.

One very good thing in the last few years that we had was a feedback meeting on sunscreen formulation technology which, I think, is the kind of meeting that needs to be held more often so that FDA can get up to date on what's being sold, how it's being made, and what the new product forms are that might benefit consumers. Next slide, please.

Another issue that needs more focus is international harmonization. We're working in a global marketplace right now. There's no way around it. It's not going to change. I think it's important that the agency focus on ways to make the international marketing of products and the availability of products across international boundaries more readily available to consumers.

I just focus here on the material tim and extent barriers. The proposed regulation that was issued earlier this year, I think, still poses major,

major hurdles to getting products into the U.S., to getting foreign ingredients into the U.S.

Labeling harmonization is very important, when you look at whether manufacturers can sell the same product across boundaries, and I think there are things the agency could do to make that easier.

One of the reasons we're so concerned about this is our products, these very products, are cosmetics in Europe and most of the world. They are drugs in the United States.

So the regulatory hurdles here are much greater than they are in other parts of the world, and although we are not necessarily arguing for a statutory change in the system here, I think there are ways that the agency can be more sensitive to that difference, and particularly with labeling, to try to grant accommodations that don't pose unnecessary barriers to international marketing. Next slide.

The solution here, I think, is increased resources, a focus on monograph issues. As I said, I don't think any change in the laws is necessary, but I think there's a lot of flexibility and leeway within FDA's existing regulations to make this all work more smoothly.

I think FDA needs to adopt a policy

encouraging more frequent communication with interested parties throughout the rulemaking process, and that's an important point. I want to stress that. Communication with the interested parties -- and I don't just mean the industry; I mean consumers and the scientific community and others -- is very important to do all the things I'm talking about in terms of updating the agency's database, and a faster review and approval of new active ingredients, both domestic and foreign. Next slide.

More outreach: I talked about international harmonization. I just want to call attention to what's called the CHIC process, which is going on now between FDA and European governments.

CFSA, the Center for Food Safety, has taken a major role in this to look for ways to harmonize on labeling. I would encourage CDER to get involved in that more than they have been in the past and to make that a high priority.

It's called cosmetic harmonization, because we're talking about these very products that are cosmetics in Europe and drugs here.

Finally, flexibility in the regulation of cosmetic drugs: If it isn't used, it can't be effective. The cosmetics industry has been able to

develop ways to make these products usable on a day to day basis. Sunscreens that are suitable for wearing to work, social events and that sort of thing as well as the beach and outdoor events where we typically think of using sunscreens -- it's important that those products be available to consumers. Next slide.

We're going to talk about two case studies, and I'm going to skip over the first one quickly, much to the relief of Dr. DeLap and Dr. Woodcock. That's OTC drug labeling.

This is a rulemaking that was applied to all OTC drugs, a comprehensive redo of the label. My only point here, because I want to give Dr. Leyden time to speak on sunscreens, is that this is a classic example of how one size fits all doesn't work for the OTC drug industry anymore, because it is such a diverse group of products.

We need labeling rules that fit these kinds of products, small packages, products that are marketed in different places, products that are marketed with cosmetic attributes, as well as labels that are appropriate for drugs that are in the middle and at the Rx end of the spectrum.

At this point, I'd like to turn it over to Dr. Jim Leyden of the University of Pennsylvania.

DR. LEYDEN: Thank you, Tom. I see by the agenda my time is up. So if I can answer any questions, I'd be glad to.

The CTFA asked if I would be willing to say a few words about the monograph process, and particular reference to these cosmetic drug categories that you just heard about, and sunscreens in particular, and I said I'd be glad to.

I was one of those who was there at the beginning. Incidentally, if it matters to anybody, I'm not receiving any honorarium for my appearance here today. I do feel that I've been part of this process. I was involved in giving seminars to many of those panels. I appeared many, many times for several panels. In fact, several of them invited me to the party that they had when their tenure was up.

The process has been long. It reminds me of my children. I have a son who is 34 and a mergers and acquisitions lawyer, and a daughter who is 36 who is an epidemiologist at Berkeley, and it was a long, hard, costly process getting them to where they are, but it was worth it.

I hope that, when the monograph process graduates in the new future, that we can look back and say it was worth it with the same enthusiasm that I

have for my children, at least.

So if we can begin. The labeling process, as you just heard, is a complex one. In the case of sunscreens, I think this is one area where commerce and public health have come together. If there's one thing we know for sure, it is that sun has acute and chronic adverse effects on skin, and the introduction of sunscreens in everyday products, I think, is an important public health step forward.

We know they can help prevent skin cancer, and we know also that they probably can help prevent some of the what are more important to many consumers, aging processes. I think prevention should be a priority for the FDA in deciding these labeling issues.

When we started back in 1972, it was simple. We had two sunscreen ingredients. We thought we knew everything there was, and we could just prevent redness, then that would be enough. This evolving process that is going to continue to evolve, as was just stressed, the need to be flexible and to adapt as new information develops, I think, is an important consideration.

We had just a couple of ingredients. We didn't UVA was important. We thought it was, quote,

"safe." We now know it's anything but safe. It plays a role in cancer. It particularly plays a role in the chronic changes associated with what we call photo-damage or photo-aging.

We know a lot more about the mechanisms of skin cancer, the wave lengths that are involved, which include both UVB and UVA. We have ways of measuring protection. That's an evolving story that some of you are more familiar with than others, and we have lots more than just traditional products first designed for when one was going to be exposed for prolonged periods of time. We have a whole variety of different products.

We have a evolving formulation technology. The sunscreens are getting better. They are lasting longer. People are learning how to make them more stable so that you can use less and have it last longer. So it's a very evolving process, and there are small units, as you just saw, lip balm things.

In fact, this morning when I was getting ready -- getting dressed, I used a shampoo that was in a small bottle, an anti-dandruff shampoo. I use an antiperspirant. I had some aspirin and Tylenol in small units, and I had some sunscreens that were in small units.

I guess none of them would be available if the kind of label that is being proposed and which has a lot of merit, I think, in many respects for some of the drugs that are available and some of the drugs you are going to be considering in the next couple of days.

These are more cosmetically oriented products, and I don't think the need to have that kind of label which would have information that's of no interest to just about anybody who would buy those products should mean the end of convenient size products.

We have a much better understanding of what sunscreens can do. They can do a lot more than just protect the acute adverse effect of sunburn. We know they can play a role in preventing skin cancer and, certainly, in preventing aging.

The aging changes, we've learned, are what really attracts the public to this concept. Telling people that it prevents cancer works. If you've had cancer or your mother had melanoma or your brother had melanoma, that makes an impact on you as an individual. But on populations -- people are much more interested in wrinkling than they are in cancer, because they think cancer is something someone else is

going to get, and everybody is going to get wrinkled and all the other changes.

So we've learned that's a very important, persuasive way of getting people interested, and mothers then get their children interested. So it's had benefits far beyond selling cosmetic products.

There are issues regarding how high SPF factors should be on labels. Many people, probably the millions of people like me, if I play golf with an SPF 30, I get burned. So I use an SPF 60, and I don't get burned. Probably I'm doing more benefit in terms of long term protection as well as preventing that acute effect.

We now know that UVA is very important. There are people -- I'm also one of those individuals who has a UVA photosensitivity, and better UVA, truly broad spectrum UVA photo-protection is indicated.

I hope the FDA will take the position, at least in this category and particularly with sunscreens, of encouraging products that help prevent problems and encouraging innovation in the labeling to attract more people to be protecting themselves in a better way as we learn more and more about how to do this more effectively.

I think this has been really a major

benefit to the public, this increasing awareness and getting more and more people aware that they can do things that protect them, not only from obvious exposure but from the enormous amount of exposure we get on an incidental basis.

It's always interesting to talk to patients who say I don't go in the sun. We say, well, do you run? Well, yeah, I run five miles every day. Do you watch your children play? Yes, I do that. You know, do you sit out, have lunch sometimes? Yes.

So incidental sun exposure is important, and protecting against it, I think, is something that should be remembered.

Hopefully, the FDA in making these rules and regulations for labeling for some of the more interesting drugs you're about to discuss over the next two days or ones that are currently available won't come out with regulations that will interfere, particularly with the sunscreen cosmetic type product that has made, I think, a big difference, and that for those of us who need high SPFs -- and we know who we are -- that that be available; and that the anti-aging benefits be allowed to be included in the labeling so that people who are more interested in that will become increasingly more aware of not only those

effects of UV but also protect themselves from the biologically more important things such as cancer.

Then finally, obviously, there's a very complex set of questions you all are having to struggle with and come up with labeling and decisions about what drugs should be available and how to protect people from simultaneously using several drugs that have the same ingredient and getting overdose effects.

In this area that seems to have somewhat fallen through the cracks a little bit in the thinking of cosmetic products that contain active drugs, I hope you will consider being more flexible, and particularly in the area of sunscreens, realize the importance of these drugs in terms of public health. Thank you. Now that my time is really up, if there are any questions.

MODERATOR DeLAP: One of the areas that I have some concerns about has to do with the labeling for sunscreen products. As these products are intended to prevent certain kinds of short term and long term damage to the skin, do we sometimes send the wrong message in labeling for products and encourage people to do things that they shouldn't?

For example, when we see discussion of how

many hours you can stay in the sun if you use an SPF 30 product and you can normally stay in the sun for X minutes, now you can stay in the sun for X hours, those kinds of things that I do see and that do concern me.

DR. LEYDEN: Yes. I think that's a very, very good point. I think recently the CTFA made a proposal of suggesting that on the label of sunscreen products be something to the effect that the fact that this makes it less dangerous to be in the sun doesn't mean that you should think that you can stay out a much longer period of time and be safe.

I mean, I think the focus of saying it makes the sun less dangerous -- I mean, nobody wants to live indoors. I want to play golf. If I played better, I wouldn't play as long as I do, but I want to play golf, you know, and not ad midnight.

So I think what we're really trying to do is find a compromise of getting people to minimize the damage, and identifying people who are much more -- There are clearly people who are more vulnerable than others, and implying that sunscreens make it safe to be outside, I think, is a mistake.

I don't think the CTFA and their members see it that way. I think their proposal of adding

that kind of further understanding of what these products do is a good one. I don't know if that's gone anywhere with the agency or not, but I think their proposal is one that I would support, and I think it fits in exactly with what you're saying.

DR. GANLEY: I just want to get a little clarification, because you mixed two different types of issues here. One is the convenience size, which actually has less labeling space, with these issues of conveying all the information the consumer needs to know through labeling.

So there seems to be some disconnect there of how you can accomplish both.

DR. LEYDEN: Well, I think having font size of the ingredients of a certain size and certain other things would be very -- might be extremely appropriate for some of the other drugs you are discussing -- is not so important in this.

I think what I was really trying to say in the few minutes there was that, instead of having that kind of information, you want to have the kind of information that people are interested in and can see and attract them to the product; because the kinds of concerns you have for some of these other drugs, I don't think, should be or are an issue with sunscreen,

particularly in cosmetic formulations.

I mean, people know what -- They have a reason why they are buying it. Some people, like my wife, likes to use cosmetic sunscreens rather than beach products when she plays golf. She's much better than I am. She's the club champion. So she likes to use a cosmetic formulation.

The people who are being enticed in the cosmetic world, many people are now using sunscreens on a regular basis because they were attracted because of the anti-aging possibilities and protection against developing further in the way of wrinkling, which I don't think is something that is currently likely to last on those products, as I understand the proposals.

So I think that kind of information for that kind of category of product would be more important than being able to see the font size of the excipients and the active sunscreen, which the average consumer doesn't really care about unless they are allergic to it, in which case they will take the time to look at small print to see if a preservative or whatever is in a given product, where the average consumer could care less, because they don't even know what those things are.

So I don't think -- Maybe I didn't have

enough time to develop it.

MODERATOR DeLAP: Dr. Temple?

DR. TEMPLE: Well, I must say, I do feel I know you and your family much better than before.

This is probably my unfamiliarity with it, but take a typical -- I don't know -- cosmetic that happens to have a little blocker in it. Is what you're saying, that should just become part of routine use. It would be a better world if more people would use those to prevent sun damage overall, and you don't need to give them a whole lot of drug facts, because they're not using it to go out and lie on their deck for many, many hours? I'm not sure I'm getting what the problem is.

DR. LEYDEN: Well, in large respect, yes. I mean, for example, we now know -- and I have some -- If we had time, I could talk for hours on this subject, as you know. We have examples of people who do not like the outdoors, but whose job gets them in front of a window, for example, on one side of their face for five or six hours, where they're getting a lot of UVA.

I have pictures of 65 and 67-year-old women, one side of their face completely caved in with wrinkles, and the other side smoother than mine.

That's clearly from indoor exposure of a large amount, you know, five or six hours a day for many years.

There are lots of people who don't go out and deliberately sun, but get a fair amount of exposure because they walk or run. They walk their dog. They watch their children. They don't think of it as sunning.

DR. TEMPLE: So how do you want the package to convey that that's different from now?

DR. LEYDEN: Well, I think any way that industry can figure out a way to attract them to use the product, I would be for, and I wouldn't try and tell them how to do it myself. I have some ideas.

DR. TEMPLE: So you think the specific language that's called for is too limiting?

DR. LEYDEN: I think so, yes.

DR. GANLEY: I have another. This may be better answered by Tom, and it deals with the regulation of products in Europe as cosmetics and products in this country as drugs.

Are you suggesting there should be a separate category of drug/cosmetics in this country or that we should adopt some of the regulations for cosmetics that Europe has for cosmetics in this country?

MR. DONEGAN: What I'm suggesting is that the regulations that you adopt should be sensitive to the fact -- to the way that these products are marketed in other parts of the world, and it's not just Europe -- and it's actually most of the rest of the world -- so that you're not creating labeling requirements, for example, that are nowhere near the same as those overseas and place a significant burden on manufacturers who want to market those across international boundaries.

I'm also saying that in cases where there are active ingredients that are used in Europe, FDA needs to expedite the process to clear those ingredients for use in the United States. That process has taken a long, long time.

I think that's a response to the realities of the international situation. I'm not asking for a different class of products. That's why I said that I don't think a change in the law is necessary. I think the way that FDA operates within the laws and regulations that it has need to more practically take into account the real world in terms of international marketing and in terms of how consumers really use these cosmetic drug products.

DR. GANLEY: To follow that up, I guess --

and Dr. Leyden can probably answer this also -- is how should we allow a consumer to distinguish between an anti-dandruff shampoo and a regular shampoo then, unless we have some specific labeling that they can easily identify that there is a difference here?

MR. DONEGAN: Well, we're not arguing that there shouldn't be drug labeling on drug products. We've never taken issue with the fact that these products are drugs and that they should be appropriately labeled for drugs.

What we're saying is that the same total comprehensive format should not necessarily be required for these drugs, and we need to look on it on a category by category basis and see if there are ways that we can reduce the amount of labeling that's necessary for these.

I mean, we also just need to be very practical about the small package issue in allowing people to market products in containers that will be used as opposed to ones that are this big, that no one is going to carry around with them. They're just not going to do it.

MODERATOR DeLAP: Dr. Kweder.

DR. KWEDER: I have a question for Dr. Leyden. Do you think that most consumers have a

general understanding of what is an appropriate protectant level of sunscreen for them, say, in a cosmetic; and if so, where do they get that information, from your perspective?

DR. LEYDEN; Well, I don't think anybody yet knows what the real answer to that question is. Red-haired, blue-eyed individuals clearly are more vulnerable than individuals who don't have blue eyes and red hair. Those who have Celtic background are clearly more vulnerable, and there are other factors in the case of melanoma.

So it's a very, very complex question. I think in the case of what information people are getting from cosmetic products, it's mainly from cosmetic companies and their representatives behind the counter and then for those who deal through other ways, through brochures or other information.

What they are being told is more is better. I don't think any of us are against that. They're not being told use a 2. They're being told use at least a 15, even if you're not going out, and if you're going to go out, use higher. So I think what information they are getting is something we can all be supportive of.

MODERATOR DeLAP: Okay. Well, thank you

very much. I think, in the interest of time, we need to move on. The next presentation is by Francesco International, Steve Francesco, President and Founder.

MR. FRANCESCO: Good morning. First of all, I want to thank the FDA for allowing me to speak at the forum. This is a historic forum and, as you'll see, my company, which is a private company -- we are not a trade association or a lobbyist -- has a great deal invested in the subject of switch.

We do publishing. Many of you have seen our newsletter called SWITCH. I believe the FDA has had a chance to review some of the issues that we sent to them. We consult. We get involved in licensing and acquisition of products involving switch areas, and we are involved in switch process management.

SWITCH, the newsletter itself, is six years old, and it's quite unique in that we cover the switch environment in the eight major markets around the world. We cover the products, the processes, the problems, and in many cases, the cultural issues.

We publish market impact studies. We have a product called the MAX planning series, and we'll talk about one particular product in detail called MAX the Molecule. We also, as I mentioned, do switch process management. Next slide.

Our company is a niche company focusing on switch. We cover every aspect of it in terms of molecules, public benefit, independent appraisals and so on. We've been influential in effecting switch policy in Canada, in Israel, and in Mexico, and I might add that, if you can go to the next slide, this company is a business, but it's also my hobby.

The principal mission is the responsible enhancement of self-medication, and on a global basis we possess a huge amount of data on switching in a number of markets. Our Website is RxtoOTCSwitch.com, as well as Franint.com. Thank you.

The issue of switching is important to us, and I'd like to expose you to this chart here which you may or may not have seen. What this represents is a global phenomenon in terms of the slow-down of switches in the major markets.

Now there's a number of pieces of information embedded in this data. By the way, the data focuses on molecule switches only. For example, nicotine patches are grouped as one, as are H2s.

What you can see is that the pace of switching from '98 and '99 is dramatically different than the previous years. You can see that, in fact, in the U.S. and in the U.K., who are historically the

leaders of switch, the pace has slowed down considerably; whereas, quite ironically, the switch champion for 1999 was France, a country which is not really well known for its switching activity.

We like to look at this from a number of standpoints. One of the most important things to remember is that embedded in these numbers are some phenomenons for the switch industry. First of all, we have the vaginal antifungals, which introduced a new concept called the initial medical diagnosis.

We have a patch which five years ago nobody ever would have guessed a patch would have been switchable. Of course, that patch is a nicotine patch which, in fact, delivers a small dose of an addictive drug to treat an addiction. Those ideas would not have been heard of five years ago.

What you can also see in this market comparison is that most everyone, not just the United States, is wrestling with the next step. What's the next direction in terms of switching, if at all? Of course, many of them are banging into the same problem of dealing with chronic therapy. Next slide, please.

This is kind of, to be perfectly honest, a "so what?" slide, but I thought I'd give you some ideas of where some switches had taken place outside

the U.S. Penciclovir and Aciclovir for cold sores are available, by and large, in Europe.

Allergy -- and I know there's an awful lot of interest in the allergy category at this meeting -- In our market, coverage of about 22 markets non-sedating antihistamines, at least one, is OTC in about 18 markets. Multiple markets also have mild steroids.

You also have cultural factors in terms of switching. As some of you may know, the morning-after pill has been switched in France. The morning-after pill is in the process of switching in the U.K., and we estimate that by 2002-2003 it will be throughout the European community as an OTC. Next slide.

The switches in Europe are often referred to as, well, it can be different because they have a third class of drugs. The third class of drugs, as was mentioned earlier, is on the decline. At this moment, the Netherlands, which is a unique country, in and of itself, is in the process of ending pharmacy-only OTCs.

In the U.K. you might say that the third class of drugs is going through a gradual meltdown. First of all, they are moving more and more drugs to general sales list, which is the equivalent of being OTC in our markets. Resale price maintenance, which

was an artificial mechanism to maintain profit, to establish guaranteed profits for local pharmacies, is under attack and highly likely to go.

In most markets in Europe the third class of drugs is on the decline for one major reason. The advice that you get from the pharmacist is declining every day, because of economic pressures. The pharmacist is behind the counter, counting the tablets, and so the concept of a third class, which was originally quite noble in the Seventies and effective, today is subsiding because of cost pressures.

So the point here is that, as we see the third class of drugs declining in the European Community, as you do in Australia, what you are also seeing is they are dealing with switch. So I want to make it clear that some of the drugs we showed you earlier in terms of the antivirals, in terms of the morning-after pill, are being reviewed in the context of a declining role for the third class of drugs.

Now this is -- My presentation, as you can see, is a little bit different from the previous trade association presentations in that I have a point of view which reflects our work on switch. Our personal belief is that a number of issues here in the United

States can be adjusted through a market mechanism. By this, I refer to the dual status of drugs.

My definition is a simultaneous Rx and OTC existence with the same brand name and with a three to six-year patent protection OTC. As you know, today most drugs in the United States are switched a year, two, maybe three years before patent expiration. We call that a life cycle extension exercise.

What we prefer to use as a strategy with our clients is not viewing it as a life cycle exercise or viewing that as a dual status product. The simultaneous Rx and OTC existence is most commonly seen as high dose/lot dose. Sometimes in the case of allergy, it can be done via perennial versus acute.

There's abundant international experience in this area to support dual status in the U.K., in France, in Germany. It's very well known there. Again, it must be perceived in the absence of a powerful third class of drugs.

In the United States we have two very clear examples I'd like to point out. Imodium back in '86 and '92 was switched well before patent expiration. You can see on the chart, at the last year -- this is where the prescription patent expired. Yet the franchise continued to grow and meet consumer

needs.

Another example is with Pepcid. Pepcid again switched well before patent expired, the concept being developed of franchise on the prescription side as well as in the OTC side. The way the growth of the curve shows, there is business on both sides and not a great deal of suffering from a sales standpoint; but as you can see, the consumer franchise opened up opportunities.

In our view, dual status solves many, many problems. First of all, with dual status reimbursement can remain. In the case recently of the H2 switching, at no point were the higher dose H2s de-reimbursed because a lower dose was available OTC.

We believe that managed care will look at dual status and will find a great deal of heat if they de-reimburse the prescription dosage because of an OTC alternative. Yet with a lower dose available, those who don't want to see an M.D., who don't want to go through the traditional system, can buy.

If you have a problem with that idea, we need to quantify that. There's a growing number of people in managed care who do not see the doctor, and this is regardless whether it's allergy or osteoporosis. The message of managed care is you'd

better take care of yourself. You'd better take care of yourself, because we won't and/or you better take care of yourself because it's your responsibility.

The option to have reasonable drugs which allow consumers to take care of themselves is very important, and we need to increase the pool for that.

At the same time, as you've seen from the previous charts, dual status expands the market for the pharmaceutical industry, who are the owners of the drugs, the developers, and the most knowledgeable.

Finally, again looking at stakeholders in context, managed care has options. Depending on the diagnosis, depending on the drug alternative, they can reimburse. At the same time, managed care is quite capable of developing an OTC reimbursement budget, a budget of $300-$500. If you want to buy your omeprazole, go right ahead.

From a pharmaceutical company's standpoint -- and this, I point out, comes from our modeling with MAX the Molecule -- time and time again, we find out that if addressed early enough and addressed objectively enough, the numbers for the companies are pretty much better if you pursue dual status as compared to a pure switch, which means a single dose, as compared to staying Rx and ultimately dying what we

call a generic death.

What this hinges on is having two product forms. The debate today in the non-sedating antihistamines often involves Claritin. It has one product form. Therefore, it can't pursue dual status. We consider it a structural flaw in the system.

If you go to the next chart, and we have a lot of information on this in the newsletter and in other sources, we've identified ten targets. We believe it's important to provide a focus to this discussion. We've gone through our work, and we've identified ten targets which we believe should be considered as targets for dual status.

They include incontinence, asthma, hypercholesterolemia, hypertension -- that should say osteoarthritis, migraine, BPH, viral infections and emergency contraception.

For perspective -- and this is, obviously, one of the issues. For perspective, many of the drugs out today in the nutritional area are addressing these sectors, and yet, as we know -- Let me put it this way. As I believe, switch drugs are better researched, have an Rx heritage, and in almost all circumstances, we believe, have a better safety margin. Next.

In summary, I'd like to expose you to this chart here. With our clients, we get a little bit academic and explain to them the history of OTC drugs. It's our point of view that we are now in the fourth stage of evolution of Rx to OTC drugs, and it's a stage which requires use of creativity at the time when you're dealing with more complex problems.

There is a great deal of a fear of change by many of the stakeholders. I've seen this week that even our journalists are being cynical and skeptical about this process before it's even started.

What I'd like to do is encourage this process to continue in an environment where looking at the treatment of chronic therapy will be viewed positively, and the people involved writing it and the people who have the stakes in it give the process the benefit of the doubt.

A final recommendation is the following: We believe dual status as a concept should have more structure around it. We believe it can solve a number of problems without rocking the system too much.

For example, there's a need to review the international switch scene in a number of areas and get up to speed as to what's being done out there. There's innovative work on chronicity being looked at

in Germany, in Sweden and in the U.K.

We believe there are a number of significant questions for which we do not have answers, and yet we don't really have a mechanism today to get those answers. So as far as we are concerned, those ten categories that I listed earlier, specific questions should be created and, on point C, incentives should be provided to the pharmaceutical companies to answer those questions.

Those questions will increase the body of knowledge significantly in dealing with chronicity in this country. The incentives to the pharmaceutical companies are designed to have those people who know the drug, who know how to do the research, and who are incentivized to answer the question.

We believe the questions should be identified and agreed to by the FDA, and the answer has to be agreed to that it was answered. It's a variation, in a sense, on Waxman-Hatch.

Finally -- By the way, I know incentives to the pharmaceutical industry are politically incorrect, but I happen to believe in them.

Finally, a number of ideas were expressed in the July summit of last year and in other meetings. I believe the concept of opening up test markets to

deal with chronicity issues for OTC are vital, and I would strongly encourage that they go in that direction. Last chart.

We are -- In a sense, our company wears our heart on our sleeve. We care about switch. We believe in it. We believe it has the possibilities of significantly enhancing public health in this country. We have products to do it, and we'd like to see this forum advance positively. And if everyone has in their heart the interest in improving public health, I'm confident that the outcome will be very positive. Thank you.

MODERATOR DeLAP: Questions? Dr. Jenkins?

DR. JENKINS: Could you expand on what you meant when you said that the Claritin situation was a flaw in the system?

MR. FRANCESCO: I should tell you a couple of things. First of all, I switched Claritin in many markets. I ran the OTC Division internationally for Schering-Plough for five and a half years. In my view, with our recommendation -- we're talking here about allergy.

What I'd like to include as categories where there's incentives to pursue dual status would be osteoporosis, hypertension and so on. In my view,

going back five, six, seven years when Claritin was going through the review process, I believe incentives should have been provided to get Schering-Plough to look for high dose/low dose. That would have made a difference.

Today, if there were a high dose/low dose available with Claritin going off patent, you can bet the low dose would be pursuing the consumer franchise right now. And there's numerous precedents for that.

By the way, one other point on the dual status. The assumption there is that the FDA does not force the switch. The assumption is that the capitalist system, the system we have today, provides incentives for the companies to pursue dual status and to pursue and answer questions which will allow the product to get into the consumer segment.

MODERATOR DeLAP: Dr. Temple?

DR. TEMPLE: Well, as you pointed out, a number of, shall we call them, devices have been used to maintain both Rx and OTC status, one of which is dose, but another of which is specific indications. So it doesn't seem out of the question to device one of those for some of the non-sedating antihistamines.

MR. FRANCESCO: Claritin in the U.K. switched. The Rx indication was perennial, and the

OTC was acute.

DR. TEMPLE: That might seem a little silly, but it's possible.

MR. FRANCESCO: No, no, no. I totally agree. I totally agree.

MR. CAMPBELL: Could you elaborate a little further on the concept of test market?

MR. FRANCESCO: One of the problems we're dealing with, with chronic therapy is that you may have plenty of evidence when you do clinical research to get the product into the prescription market. At that point you have the learned intermediary involved. You don't have the physician involved in the OTC side in a particular format. There are other formats like initial medical diagnosis, you could. But in the purest sense, you don't.

There are numerous companies in the United States that are experts at identifying markets to test their products. They are as banal as Pampers, and I spent a lot of my years working on Pampers. They are as banal as underarm deodorants.

If we could identify a population that we feel safe should get exposed to products under certain conditions -- and I'm specifically referring to chronic drugs here; let's call it a third class of

consumer. So there will be a third class of drugs. Let's call it a third class of consumer.

This is a group in Atlanta, Seattle, whatever, who have through proper screening been exposed to -- they've been found to be okay to take this drug. They're going to get certain types of labeling, certain types of packaging, and it's going to be fairly strictly controlled. Let's see how they respond to the drug.

Linked to that could be some of the bigger issues of monitoring and compliance with OTC drugs. Let's create population samples. That's the concept. I am by no means an expert on this today, but I think the idea has a great deal of merit, and I think it will help address many of the problems you're going to deal with in dealing with chronic therapy.

DR. GANLEY: Could you just expand a little bit on the answer you gave regarding the FDA taking the initiative to bring products Rx to OTC without the company really agreeing to it. It seems that, if it's in the public interest and best for public health, that that should be paramount rather than just based purely on economics.

MR. FRANCESCO: What is well established in markets outside the U.S. is that the Board of

Health has the ability to force a switch, and it's based upon two reasons. One, it's written in their charter but, number two, they are the insurance companies.

So that last year Sweden for the first time really, and I think perhaps in history, forced a switch of omeprazole. It's a pharmacea product. It was a Swedish product. Surprised us all. There are other areas where drugs are being switched which are a little bit less controversial, vein tonics in France.

So that governments outside the U.S. do have the power, clearly have the power, but it's based upon the fact that it's cost driven. They are trying to reduce reimbursement, since they are the insurance companies.

Here in the United States the system is a private insurance system. I have a hard time seeing the initiative driven here on the basis of cost, since you're not the insurance system. Therefore, it has to be driven by something else.

My personal belief is in the capitalist system that we have today, if you provide financial incentives to the pharmaceutical companies, they will move. So in my perspective, rather than creating a

whole series of legislative proposals, ties up in court and so on and so forth, provide a simple incentive.

For example, $300 million goes into research before a product gets into approval, generally speaking. The questions we deal with on switching are much more banal, for the most part, by comparison, much simpler. A cost could be $15 million on top of the 30. So it becomes 315, but that $15 million gives you important information on what would happen if that drug went into the consumer market, and particularly addressing issues like monitoring and compliance, which are very big issues.

I think that they are prepared to do the research. My preference, if you give them the tax incentive the first year of the prescription launch -- give it to them early. You saw my charts on net present value. Pharmaceutical companies will say we'll get that break now. You run that out. It's a lot of money.

I think that's going to be a better mechanism for getting switches done properly and researched, rather than having a mandate from the government. I do understand the frustration you feel of having certain drugs you think should be switched.

I prefer a market mechanism.

Not only do I prefer a market mechanism because of the system we have today. I think the market mechanism will do a better job of getting switches going, and it will increase the number dramatically.

If you take those ten categories I listed and you say there's four products that are candidates, you now have 40 candidates for switch that are going to be researched, and our body of knowledge in this area will grow dramatically.

DR. WOODCOCK: And you're saying that the market mechanism would be to formalize some type of dual system?

MR. FRANCESCO: I'm not a lawyer, and this gets very tricky. The basic concept is there's an agreement with the FDA that we want to know that this drug being used by the consumer without doctor intervention is working. They are complying with it, and it's having an effect.

There are ways of structuring that test market, if you will. If the answer is, guess what, this works, then there's a reward. The point is the research should be done early, because that feeds dual status, and that allows the trigger down the road.

DR. WOODCOCK: What is the reward?

MR. FRANCESCO: The reward for the pharmaceutical company is a tax break. It's a tax incentive. They spend $15 million on research. They get a $30 million tax break the first year, but that product is ready.

I know this is politically incorrect, but that product is ready to be switched much earlier, and companies have dealt with problems much earlier, and it may reach the market five to six years earlier than just before patent expiration.

MODERATOR DeLAP: Dr. Temple?

DR. TEMPLE: Could you talk a little bit, especially in relation to the potential chronic uses, about something that's come up already today and comes up all the time. That is the possibility that you encourage people to use one out of a series of alternatives.

Just as an example, suppose low dose diuretics became available for the treatment of hypertension. Low dose diuretics might not be the first thing you should use. Maybe you should use an ACE inhibitor.

We, being doctors, tend to think of those as sophisticated decisions that require our input.

What's your view about questions like that?

MR. FRANCESCO: My view is I agree with you that there's a lot of questions. The answer here is are we getting the answers that we need, and are we getting them soon enough?

I hate to refer to this publication again, but we've listed here about 25 questions where I believe we don't have decent answers. So your question is very valid. We need a mechanism to get those answers, and that's what I'm talking about.

MODERATOR DeLAP: One more question from Dave Fox.

DR. FOX: Just curious about what your view is of three-year exclusivity under Waxman-Hatch as an incentive for a sponsor to move over-the-counter. Is that enough? Too little?

MR. FRANCESCO: I'm not sure I heard the whole question. I'm sorry. Exclusivity in Waxman-Hatch?

DR. FOX: Yes. The potential to gain three years of market exclusivity on the over-the-counter market if one does clinical studies that are necessary to the switch as an incentive to encourage sponsors to pursue a switch. What's your view of that? That's an incentive that already exists in the

statute, conveniently.

MR. FRANCESCO: The incentive to gain additional patent protection just prior to patent expiration is a terrific incentive to a pharmaceutical company to defend against generics. There's nothing inherently wrong with that.

My question is: Is that going to affect the issues of chronicity? Is that going to give you the information you need in dealing with osteoporosis? Those kinds of problems have a much longer time frame to solve. They cost a lot more money.

So that my feeling on the dual status proposal is that it should not at all be linked with Waxman-Hatch. I think it should be a separate issue. The other reason I don't think it should be linked with Waxman-Hatch is Waxman-Hatch has a lot of other baggage to it. I would prefer to look at this one as a clean, simple idea. Does that answer your question?

MODERATOR DeLAP: Thank you very much.

Rather than proceeding to the next presentation now, I think it would be a good time to take a 15-minute break, but we will reconvene promptly at 10:45.

DR. TITUS: And we just want to announce that we have a second site. We realize that the room

is crowded, and you might want to go to our second site, which is in Rockville. You can ask at the front desk for direction.

(Whereupon, the foregoing matter went off the record at 10:31 a.m. and went back on the record at 10:54 a.m.)

MODERATOR DeLAP: Okay. Again, if people can please be seated, we will get underway.

We'll start up now with the presentation from the Consumers League, and Linda Golodner and Brett Kay. I'll turn it over to Linda now. Thank you.

MS. GOLODNER: Thank you very much. The National Consumers League is pleased to present the consumer's viewpoint on over-the-counter drugs and switch issues.

As everyone is aware, information, a lot of information, is available to consumers through the media, through patient and consumer groups, at the drugstore, from the doctor, and now through the Internet. It's not neat. There's a lot of information. There's a heap of information available, but consumers really need help in understanding that information.

It doesn't help that we're now in a

managed care system that often does not encourage the communication of the health care professional with the patient.

I know the FDA is very much aware of safety concerns, especially with prescription drugs and over-the-counter drugs and dietary supplements and foods interacting, and that there's not enough information for consumers to make some choices when they are taking these products.

The FDA, I think, has been very strong in its position to make sure that consumers do have information on a label, and is strong in their position that information is in a large-sized type. Sometimes the only information that a consumer has between the product, actually taking the product and the -- with the over-the-counter drugs is that information on the label, and it must be in a size type. It must be available so that they can read it.

It is particularly true with some of the over-the-counter drugs that are considered now for switch. For instance, if a drug for osteoporosis or for cardiovascular disease is over-the-counter, we want to make sure that those people who would be taking it can read it.

We would also encourage that the FDA move

closer to making sure that information is available to consumers in languages other than English.

Who else is responsible for educating the consumer? Obviously, consumer and patient groups do it, but the health care professionals are the ones on the line who must be there to help consumers understand the drugs that they are taking.

It is not only the responsibility of the health care professionals, but those that manage the health care professionals in managed care organizations, in drugstores, managers of food stores, managers of discount stores that provide this product to make sure that there are enough pharmacists there who can talk to consumers and can work in reasonable hours so that they can actually have this communication with consumers.

It's also important that there be greater communication between the doctor and the patient.

The National Consumers League has done a couple of surveys in the last month -- and we will make the cross-tabs available to the FDA as part of the record -- that we want to share with you today.

Some of the things that we were concerned about are the great deal of information that's available to consumers, how are they using it, are

consumers using OTCs appropriately; what OTCs do consumers want, and what about statins and cardiovascular disease; and what's the consumer responsibility, and where do consumers actually get their information now when they do use an over-the-counter drug.

In the first survey, we commissioned Yankelovich Partners. They did a random sample survey that's a plus or minus three margin of error. These respondents were at least 18 years old, and these interviews were done between May 15 and May 31 this year.

We asked, compared to five years ago, are you making decisions on your own, and 58 percent of consumers said that, yes, that they are making more decisions on their own. However, when we asked seniors, 52 percent of them -- that's about half seniors -- are making more health decisions on their own.

We asked consumers the first thing they do when facing a minor ailment, and we listed some minor ailments like headaches or stomach aches. Half of the people rely on their own self to make that decision. Twenty-two percent said doctors and themselves. Ten percent rely only on the doctor, and seven percent

rely on a pharmacist and themselves. Some just rely on the pharmacist.

We asked them, when you treat yourself, what is the preferred treatment? Fifty-seven percent said an OTC. Some like to cure themselves naturally. They want that headache to go away, and they just wait, and it actually does go away. Sixteen percent, though, are using dietary supplements.

We asked them what resources they use to decide which OTC to take, and we got -- these were multiple answers. 66 percent depend on the label. Others talk to their doctor, friends and relatives, the pharmacist. Fifty-two percent also asked their pharmacist, and so on. Ten percent do actually go to the Internet for some information, but I don't think they -- in some other questions we asked, they don't rely on it 100 percent.

We asked how often do you generally read the labels on OTCs. Always or nearly every time, 66 percent. But if you combine the 66 percent and the 17 percent of "most of the time," you end up with 83 percent always or most of the time reading those labels. Of this, though, 75 percent of seniors read the labels always or most of the time. We also found that females are reading more labels than males.

We also asked how easy are the labels of OTCs to read and understand. Very easy, 44 percent; somewhat easy, 31 percent. We found that a combination of somewhat difficult and very difficult, 17 percent feel that it is difficult to read. This is one in four people are having a problem with reading the OTC label and understanding it, and this increases with age.

We found that it's not only the 85-year-olds who are having trouble reading those labels, but that 35 and above have more difficulty than those that are younger.

We also asked how often do you read information inside the package. Thirty-seven percent said always or nearly every time, and most of the time, 21 percent. So there's a better information that consumers are seeing inside the package, but they're not -- Some of them read it. However, when we asked -- I don't have a slide on this -- When we asked about if they understood it, less people do understand that information that's inside the package.

One interesting question we asked is how often, if ever, have you taken more of an OTC med than was recommended on the label, such as taking four pills when two pills are the recommended dose.

Fourteen percent said always or most of the time, that they do take more than is recommended -- the recommended dose. However, half of the people say that they never do this.

We also asked if they had taken OTCs longer than recommended. As you know, on several labels it says don't take for more than three days or seven days. Nine percent of the people said always or most of the time that they do take it longer than is recommended. However, 63 percent said that they never do this.

We also asked how satisfied you are with the range of medications that are over-the-counter. Twelve percent said they are extremely satisfied; 39 percent, very satisfied.

We asked whether OTCs are safer than prescription meds, and 25 percent said that they think they are safer. The younger people, 18-34, 29 percent said that these are safer than prescription drugs.

WE also asked if you had to pay attention to the OTC labels -- if you don't have to pay attention to labels, and 89 percent agreed -- disagreed with that. Ten percent felt that you don't have to pay attention to them.

We also asked whether there are problems

with OTCs interacting with prescription medications, and 16 percent said, yes, there are no problems with this. Seventy-eight percent, though, disagreed with this.

We also asked if you wished some of your prescription meds were OTC, and 65 percent said yes. Seventy-two percent of those were in the over-$75,000 a year category as annual income; 69 percent were of younger age, 18-34.

We also asked what meds they would like over-the-counter, and we don't have that information back, but I just did look at -- I looked at the raw material, and they are looking at non-sedating allergy drugs and hypertension drugs as those that they would like to see over-the-counter.

Now my colleague, Brett Kay, is going to make a presentation on a second survey that we did.

MR. KAY: Thank you. We have data from this, and also we wanted to look at some of the data previously that we've done over the past couple of years, which is leading up to why we're here today. Consumers are concerned about OTCs. They are concerned about their health care.

Over several years now we've had two different surveys over the past two years that have

said that consumers -- 86 percent of consumers feel that having an increased role in their own health care is positive.

Then when we focused more specifically on cardiovascular disease, which is still the leading cause of death and disability in the United States, the numbers are even stronger. Eighty-eight percent said they would like to know as much as possible about lowering their risk of coronary heart disease.

Sixty-four percent of Americans are confused about how to live a healthy lifestyle, and are confused and overwhelmed by all the information out there on how to lower their risk, what to do about diet and exercise. They know there is something they should do, but they are not exactly sure what to do because of some of the overload of information. I don't think this comes as a great surprise to anyone.

Fifty-two percent did not know their cholesterol level, and that's over the past couple of years, and that's consistent with data which I'll show you also right now from the survey that we got -- that we just back the results the other day. Eighty-five percent cited their doctor as the most reliable source of information about lowering their risk for coronary heart disease.

Because of this continued confusion about coronary heart disease and cholesterol, and because of the fact that it shows that consumers are taking a much more active role in their decision making, we feel that it is important to understand the consumer attitudes toward possible OTC, specifically the cholesterol lowering medications. We wanted to see also how a new OTC product really would be perceived and how consumers say they would use such a product.

Let me get to some of the data on this. This survey was commissioned by Opinion Research Corporation International. It was a random-digit dial sample of 1,000, plus or minus 3.1 margin of error. The interviews were conducted June 7-18.

The two screeners that we had originally were -- they are 35 and older, and we asked the question are you somewhat or very concerned about your cholesterol level. Also, Lou Morris from SPC Communications helped to design the survey and analysis for us with this.

The survey topics: Again, there's a sample description. We talked about disease prevention, what activities people are doing, what information they are getting, what they want, and then finally attitudes about treatment in general and then

specifically about cholesterol treatment, and even more specifically about an OTC cholesterol treatment, whether it's a good idea or a bad idea, and how they would use it.

Some of the sample demographics, as you see. Of the two columns, notice the first column is the total, and this will be consistent for all the slides you'll see, is the total weighted data. Then the second two columns are one of the questions we asked was -- and we use it as one of the banners -- is would you be personally interested in a low dose over-the-counter cholesterol medication if it were made available? Would you be interested or not interested?

So the first number you see there would be the interest in it, and second would be not interested. Where you see an asterisk, there's a statistically significant difference at the 95 percent confidence interval. We have further data. I'd be happy to talk about that later, if you want.

When we pulled out for female, 56 percent of the total was female, the majority 55+. It was 41 percent. Fifty-nine percent of our demographic population had some or more college education, and an income of $35,000 or more.

Some of the psychographic data -- and this

is consistent with previous surveys that we have done and data that we have found: About 49 percent, about half the population knows their cholesterol levels. Forty-one percent believe their cholesterol level is high, and another third believe that they are at risk because of their cholesterol levels.

Encouragingly, 81 percent have visited their doctor within the last year. In our sample population, 91 percent had health insurance, and 89 percent had Rx drug coverage.

Some of the disease prevention activities: We asked what are people doing to prevent disease, and again these are consistent with other findings that we've had throughout the past few years: 73 percent are exercising; 67 percent are visiting the doctor.

People are taking an increasing amount of vitamins. They are also taking prescription drugs, aspirin to prevent a heart attack. They are taking OTC drugs. Then we asked about garlic, fish oil and other such supplements that relate to heart disease or cholesterol lowering. Again, nearly a third of the people are taking such a product.

Then we asked the question for disease prevention information: Where did you get your information, and what do you look for? Sixty-nine

percent are looking at nutrition labels. They are starting to read the fat content and things on the nutrition facts panels. They are talking to their doctors. They are reading drug labels, and then about less than half are getting it from magazine articles, newspapers.

On this recent survey, you'll notice 23 percent are looking to the Internet. So that trend, I think, is starting to grow and probably will continue to do so as it becomes a more mainstream media content channel.

Now we had some general attitudes regarding treatments in general, especially for heart disease. What are some of the things that you do to prevent or to get treatment, and how do you feel about it? Eighty-five percent still feel that the doctor knows best.

People are concerned. Sixty-one percent are concerned that Rx drugs cause too many side effects. They don't like -- 60 percent don't like to take them. Forty percent feel more comfortable taking an OTC drug than an Rx drug. Again, 28 percent -- as you saw previously it was 25 percent -- feel OTCs are safer than an Rx, and 21 percent think that it's more effective.

Now we asked specifically about cholesterol treatment attitudes, and this is a combination of strongly and somewhat agree to questions. Reducing cholesterol will add years to my life: 94 percent, as you can see, think that this is a good thing. So at least the cholesterol message is getting out there, and consumers are aware of it.

Then the second question also, that high cholesterol is a serious threat to your health, also shows that this message is continuing to get out there.

Some of the ones I thought are interesting: 75 percent, three-fourths of the population, will seek advice of their doctor on a regular basis about this. Then another 69 percent feel that their doctor gives them advice, but they make their own decision, which is continuing to show the trend of people taking more control over their own health care.

Fifty-one percent, again consistent, find information about cholesterol confusing, which is consistent with our other findings from last year and the year before.

We asked the question straight up, if a low-dose prescription -- nonprescription cholesterol

treatment were made available, would that be a good idea or a bad idea? Overwhelmingly, by a two to one margin, consumers said it was a good idea, and statistically, you can see in the second column, 82 percent would be interested in such a product compared to 41 percent not interested who said that. Obviously, in the bad idea category, the numbers are reversed, which is at least consistent.

Then we sort of broke down why it would be a good idea and why it would be a bad idea. Expense was cited as the number one reason; that it would be more readily available. Under that we combined a lot of the categories from the raw data into these, under readily available such as they don't have to see a doctor, it's easier, it's less time consuming, along those lines. They feel that it would help lower the cholesterol.

For the bad idea, people feel that it's really important, 44 percent, that they need to consult their doctor before something like this, and also people are concerned that they wouldn't know how to take it properly.

Now this goes to some of the attitudes and actual use, and I think this is some of the important data around what would people actually do if this were

made available. I know there are a lot of concerns of would people continue to see their doctor, would people continue to have follow-ups and check-ups.

Ninety-one percent, an overwhelming majority, said that they would still talk to their doctor if this drug were available and they were using it. Again, 83 percent would talk to their pharmacist, which is good.

Fifteen percent wouldn't have to watch what they eat, and 11 percent said they would see their doctor. So you're talking about really a very few people would really neglect the doctor's health advice, which I think is encouraging to see.

Again now, if directed on a label to see the doctor prior to use on the package label, what would people do? Eighty-seven percent said they would only use it if the doctor said it's okay, and 86 percent would consult it before the doctor.

So again, people have a strong desire to continue the doctor-patient relationship and follow up with the labeling.

I'm just going to go through this next one quickly to the confidence question. Confident I can use it correctly was the question we asked. Do you feel that you could use this properly? Seventy-six